



09/674733

C of C

UNITED STATES PATENT AND TRADEMARK OFFICE

Atty. Docket: SZARDENINGS=1

|                              |   |                      |
|------------------------------|---|----------------------|
| In re Patent of:             | ) | Conf. No.: 3759      |
|                              | ) |                      |
| SZARDENINGS et al.           | ) |                      |
|                              | ) |                      |
| Patent No.: 7,008,925        | ) | Washington, D.C.     |
|                              | ) |                      |
| Issued: March 7, 2006        | ) | April 20, 2007       |
|                              | ) |                      |
| For: MELANOCORTIN 1 RECEPTOR | ) |                      |
| SELECTIVE COMPOUNDS          | ) | ATTN: Certificate of |
|                              | ) | Correction Division  |

REQUEST FOR EXPEDITED CERTIFICATE OF CORRECTION UNDER 37 C.F.R.  
§1.322

Honorable Commissioner for Patents  
U.S. Patent and Trademark Office  
Randolph Building, Mail Stop Post Issue  
401 Dulany Street  
Alexandria, VA 22314

**Certificate**

APR 24 2007

**of Correction**

Sir:

In checking over the printed copy of the above-identified patent, we have found the following error that is the fault of the Patent and Trademark Office. It is respectfully requested that this error be corrected in accordance with 37 CFR §1.322(a). The error to be corrected is listed below.

The PTO erred by publishing, as the sequence listing for this case (cols. 39-46), a sequence listing associated with some other case. This is evident from comparison of cols. 39-46 with the 8 page sequence listing filed June 12, 2001.

APR 25 2007

In re of U.S. Patent 7,008,925

|                     | <u>Cols. 39-46</u>      | <u>June 12, 2001</u>            |
|---------------------|-------------------------|---------------------------------|
| Number of Sequences | 22                      | 15                              |
| SEQ ID NO: 1        | 30 base<br>DNA sequence | 13 a.a.<br>Polypeptide sequence |
| SEQ ID NO: 2        | 10 base<br>DNA sequence | 13 a.a.<br>Polypeptide sequence |

and so forth.

It is important that the error be corrected because one or more of SEQ ID NOS: 1-15 are referred to in claims 9 or 10.

We are attaching one copy of the Certificate of Correction form.

In accordance with MPEP §1480.01, in an effort to expedite processing of this request, copies of cols. 39-46 of the patent, and the June 12, 2001, filing are attached, so that the PTO can verify that an error was made. Consequently, correction should be expedited pursuant to MPEP §1480.01.

Granting of this request is earnestly solicited.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.  
Attorneys for Applicant(s)

By

  
Iver P. Cooper  
Registration No. 28,005

:dtb

Telephone No.: (202) 628-5197

Facsimile No.: (202) 737-3528

G:\ipc\n-q\Plou\Szardenings1\2007-04-20CertCor322PTOFault.doc

APR 25 2007

UNITED STATES PATENT AND TRADEMARK OFFICE  
CERTIFICATE OF CORRECTION

Page 1 of 13

PATENT NO. : 7,008,925  
APPLICATION NO.: 09/674,733  
ISSUE DATE : March 7, 2006  
INVENTOR(S) : SZARDENINGS et al.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Please delete the sequence listing at cols. 39-46 and insert therefor the following sequence listing:

SEQUENCE LISTING

<110> Szardenings, Michael

Muceniece, Ruta

Mutule, Ilze

Mutulis, Felikss

Jarl, Wikberg

<120> Melanocortin 1 Receptor Selective Compounds

<130> 1085.0050000/RWE/ALS

<140> 09/674,733

<141> 1999-05-05

MAILING ADDRESS OF SENDER (Please do not use customer number below):

624 Ninth Street, NW  
Suite 300  
Washington, DC 20001-5303

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**UNITED STATES PATENT AND TRADEMARK OFFICE  
CERTIFICATE OF CORRECTION**Page 2 of 13

PATENT NO. : 7,008,925  
APPLICATION NO.: 09/674,733  
ISSUE DATE : March 7, 2006  
INVENTOR(S) : SZARDENINGS et al.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

&lt;150&gt; PCT/GB99/01388

&lt;151&gt; 1999-05-05

&lt;150&gt; SE 9801571-2

&lt;151&gt; 1998-05-05

&lt;160&gt; 15

&lt;170&gt; PatentIn version 3.0

&lt;210&gt; 1

&lt;211&gt; 13

&lt;212&gt; PRT

&lt;213&gt; Artificial

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**APR 25 2007**

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Page 3 of 13

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APPLICATION NO.: 09/674,733  
ISSUE DATE : March 7, 2006  
INVENTOR(S) : SZARDENINGS et al.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

&lt;220&gt;

&lt;223&gt; Synthetic peptide with high affinity for melanocortin receptor 1

&lt;400&gt; 1

|     |     |     |     |     |     |     |     |     |     |     |     |     |
|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Ser | Ser | Ile | Ile | Ser | His | Phe | Arg | Trp | Gly | Lys | Pro | Val |
| 1   |     |     |     | 5   |     |     |     |     | 10  |     |     |     |

&lt;210&gt; 2

&lt;211&gt; 13

&lt;212&gt; PRT

&lt;213&gt; Artificial

&lt;220&gt;

&lt;223&gt; Synthetic peptide with high affinity for melanocortin receptor 1

&lt;220&gt;

&lt;221&gt; MOD\_RES

&lt;222&gt; (7)..(7)

&lt;223&gt; D amino acid

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ISSUE DATE : March 7, 2006  
INVENTOR(S) : SZARDENINGS et al.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

<400> 2

Ser Ser Ile Ile Ser His Phe Arg Trp Gly Lys Pro Val  
1 5 10

<210> 3

<211> 14

<212> PRT

<213> Artificial

<220>

<223> Synthetic peptide with high affinity for melanocortin receptor 1

<400> 3

Tyr Ser Ser Ile Ile Ser His Phe Arg Trp Gly Lys Pro Val  
1 5 10

<210> 4

<211> 13

<212> PRT

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ISSUE DATE : March 7, 2006  
INVENTOR(S) : SZARDENINGS et al.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

<213> Artificial

<220>

<223> Synthetic peptide with high affinity for melanocortin receptor 1

<400> 4

Tyr Ser Ile Ile Ser His Phe Arg Trp Gly Lys Pro Val  
1 5 10

<210> 5

<211> 14

<212> PRT

<213> Artificial

<220>

<223> Synthetic peptide with high affinity for melanocortin receptor 1

<400> 5

Ser Ser Ile Ile Ser His Phe Arg Trp Gly Lys Pro Val Tyr  
1 5 10

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Page 6 of 13

PATENT NO. : 7,008,925  
APPLICATION NO.: 09/674,733  
ISSUE DATE : March 7, 2006  
INVENTOR(S) : SZARDENINGS et al.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

<210> 6

<211> 12

<212> PRT

<213> Artificial

<220>

<223> Synthetic peptide with high affinity for melanocortin receptor 1

<400> 6

Ser Ile Ile Ser His Phe Arg Trp Gly Lys Pro Val  
1 5 10

<210> 7

<211> 13

<212> PRT

<213> Artificial

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Page 7 of 13

PATENT NO. : 7,008,925  
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ISSUE DATE : March 7, 2006  
INVENTOR(S) : SZARDENINGS et al.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

<220>

<223> Synthetic peptide with high affinity for melanocortin receptor 1

<400> 7

Thr Ser Ile Ile Ser His Phe Arg Trp Gly Lys Pro Val  
1 5 10

<210> 8

<211> 13

<212> PRT

<213> Artificial

<220>

<223> Synthetic peptide with high affinity for melanocortin receptor 1

<400> 8

Ser Thr Ile Ile Ser His Phe Arg Trp Gly Lys Pro Val  
1 5 10

<210> 9

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Page 8 of 13

PATENT NO. : 7,008,925  
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 ISSUE DATE : March 7, 2006  
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It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

&lt;211&gt; 13

&lt;212&gt; PRT

&lt;213&gt; Artificial

&lt;220&gt;

&lt;223&gt; Synthetic peptide with high affinity for melanocortin receptor 1

&lt;400&gt; 9

|     |     |     |     |     |     |     |     |     |     |     |     |     |
|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Ser | Ser | Val | Ile | Ser | His | Phe | Arg | Trp | Gly | Lys | Pro | Val |
| 1   |     |     |     | 5   |     |     |     |     | 10  |     |     |     |

&lt;210&gt; 10

&lt;211&gt; 13

&lt;212&gt; PRT

&lt;213&gt; Artificial

&lt;220&gt;

&lt;223&gt; Synthetic peptide with high affinity for melanocortin receptor 1

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ISSUE DATE : March 7, 2006  
INVENTOR(S) : SZARDENINGS et al.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

<210> 11

<211> 13

<212> PRT

<213> Artificial

<220>

<223> Synthetic peptide with high affinity for melanocortin receptor 1

<220>

<221> MOD\_RES

<222> (1)..(1)

<223> ACETYLATION

<400> 11

Ser Ser Ile Ile Ser His Phe Arg Trp Gly Lys Pro Val  
1 5 10

<210> 12

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<211> 13

<212> PRT

<213> Artificial

<220>

<223> Synthetic peptide with high affinity for melanocortin receptor 1

<220>

<221> MOD\_RES

<222> (1)..(1)

<223> D amino acid

<400> 12

Ser Ser Ile Ile Ser His Phe Arg Trp Gly Lys Pro Val  
1 5 10

<210> 13

<211> 13

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It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

<212> PRT

<213> Artificial

<220>

<223> Synthetic peptide with high affinity for melanocortin receptor 1

<220>

<221> MOD\_RES

<222> (1)..(1)

<223> N-Methyl-L-Serine

<400> 13

|     |     |     |     |     |     |     |     |     |     |     |     |     |
|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Ser | Ser | Ile | Ile | Ser | His | Phe | Arg | Trp | Gly | Lys | Pro | Val |
| 1   |     |     |     | 5   |     |     |     |     | 10  |     |     |     |

<210> 14

<211> 13

<212> PRT

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<213> Artificial

<220>

<223> Synthetic peptide with high affinity for melanocortin receptor 1

<220>

<221> MOD\_RES

<222> (13)..(13)

<223> MeVal

<400> 14

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1 5 10

<210> 15

<211> 13

<212> PRT

<213> Artificial

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<220>

<223> Synthetic peptide with high affinity for melanocortin receptor 1

<220>

<221> MOD\_RES

<222> (7)..(7)

<223> N-Methyl-D-Phenylalanine

<400> 15

Ser Ser Ile Ile Ser His Phe Arg Trp Gly Lys Pro Val  
1 5 10

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2 5 2007

## Cell Culture

RAW 264.7 cells (TIB-71), obtained from American Type Culture Collection, 12301 Parklawn Drive, Rockville, Md., 20852, USA, and cultured in Dulbecco's modified Eagle medium (Gibco, BRL) supplemented with 10% heat-inactivated fetal bovine serum, 100 IU penicillin/ml and 100 µg streptomycin/ml at 37° C. in a humidified atmosphere of 95% air and 5% CO<sub>2</sub>. Cells grown in monolayers were detached from the culture flasks and collected by low speed centrifugation (700×g).

## Incubation of Compounds of the Invention with RAW 264.7 Cells

The cells obtained as above were resuspended in F-12 (HAM) medium (Gibco, BRL) and distributed into 96-well plates at a density of  $2.5 \times 10^6$  cells per well, and incubated with 100 ng/mL bacterial lipopolysaccharide (L4391, Sigma Chemical Company, P.O. Box 14508, St. Louis, Mo. 63178, USA), 5 units/mL of mouse recombinant interferon gamma (15517, Sigma Chemical Company, P.O. Box 14508, St. Louis, Mo. 63178, USA) and the compounds of the invention using concentrations ranging 01 µM, for 16 h, whereafter an aliquot of the medium was collected for measurement of nitric oxide (NO).

## Measurement of Nitric Oxide

Nitric oxide was measured by monitoring the nitrite production essentially using the method of Wishnok et al. (Methods in Enzymology, 1996, 268, 130–151). In brief 50 µL of culture medium was mixed with 50 µL Griess reagent (i.e. a 1:1 mixture of 0.1% N-naphthylethylenediamine dihydrochloride and 1% sulfanilamide in 5% (v/v) phosphoric acid) and after 10 min the absorption was measured at 540 nm. The nitrite concentrations were calculated from a standard curve constructed, by instead of culture medium, adding 50 µL of between 3 to 100 µM of NaNO<sub>2</sub> to the assays.

## 15 Results

The results are shown in FIG. 6. As can be seen from the Figure, the compounds of the invention, MSO5 and MSO9, as well as α-MSH caused a strong dose dependent inhibition of the NO-production, the potencies and efficacies of MSO5 and MSO9 being similar to that of the α-MSH. This data shows that MSO5 and MSO9 share the capacity of α-MSH to inhibit inflammation. This is because NO is a key component of inflammation.

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JUL 25 2007

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# COPY

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



In re application of:

Szardenings *et al.*

Appl. No. 09/674,733  
(U.S. Natl. Phase of PCT/GB99/01388)

Int'l Filing Date: May 5, 1999

For: **Melanocortin 1 Receptor  
Selective Compounds**

Art Unit: *To be assigned*

Examiner: *To be assigned*

Atty. Docket: 1085.0050000/RWE/ALS

### **Amendment and Submission of Substitute Sequence Listing Under 37 C.F.R. § 1.825(a)**

Commissioner for Patents  
Washington, D.C. 20231

Sir:

In compliance with 37 C.F.R. § 1.825(a), Applicants submit substitute sheets to amend the paper copy of the Sequence Listing.

#### ***In the Specification:***

Please cancel the existing Sequence Listing for the above-identified application, replace it with the substitute Sequence Listing appended hereto, and insert the same at the end of the application.

#### ***Remarks***

Applicants' Agent hereby states that the change made in the sequence listing does not include new matter. Applicants' undersigned Agent has amended the specification only to direct the entry of this corrected Sequence Listing at the end of the application.

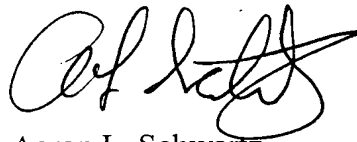
APR 25 2007

In accordance with 37 C.F.R. § 1.825(b), the paper copy of the Sequence Listing and the computer readable copy of the Sequence Listing submitted herewith are the same.

It is respectfully believed this application is now in condition for allowance. Early notice to this effect is earnestly solicited.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Aaron L. Schwartz  
Agent for Applicants  
Provisional Registration No. P-48,181

Date: 6/12/01

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Washington, D.C. 20005-3934  
(202) 371-2600

P:\USERS\Schwartz\Cases\1085\005\pto\825 amendment.wpd

APR 25 2007

SEQUENCE LISTING



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SEP 25 2007